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EXAMINER	
LUCAS, ZACHARIAH	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/809,060	WILD ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *9-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3- see action*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on September 12, 2005 is acknowledged. The traversal is on the ground(s) that there would be no undue burden on the Office in the examination of each of the claimed inventions. This is not found persuasive because each of the inventions is drawn to a separate invention, each of which requires a search and examination no co-extensive with the other inventions, and which would not produce art sufficient to determine patentability of the other inventions.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 9-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 12, 2005.

3. Claims 1-8 are pending and under consideration. Further, upon further consideration, claim 30, which also reads on complex of the envelope protein and stabilizing peptide (optionally including a soluble cell receptor for the envelope protein), this claim is rejoined with the inventions of claims 1-8.

Information Disclosure Statement

4. The information disclosure statements (IDS) submitted on May 25, 2001, February 26 and April 16, 2002, are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

5. The following reference is in a foreign language accompanied by an English abstract. Due to this, the reference has been examined only to the extent of the disclosure in the abstract.

WO 92/19742.

Specification

6. The specification is objected to for referring to protein or nucleic acid sequences without also identifying them by the sequence identifier assigned to them in the sequence listing as required by 37 CFR 1.821(d). See e.g., p. 23, line 6. The examiner would like to bring the applicant's attention to the following excerpt from MPEP §2422.03:

> 37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences regardless of whether a given sequence is also embedded in the text of the description or claims of an application. This requirement is also intended to permit references, in both the description and claims, to sequences set forth in the "Sequence Listing" by the use of assigned sequence identifiers without repeating the sequence in the text of the description or claims. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as "residues 14 to 243 of SEQ ID NO: 23" is permissible and the fragment need not be separately presented in the "Sequence Listing." Where a sequence is embedded in the text of an application, it must be presented in a manner that complies with the requirements of the sequence rules.

The applicant is therefore required to amend the specification to comply with 37 CFR 1.821(d).

7. The disclosure is objected to because of the following informalities: the application refers on page 63 to Figure 4B as showing reduction in viral replication in a conducted assay. However, this Figure shows the structure of the trimer of hairpins of gp41, not results of a neutralizing assay. It appears that the application intended to refer to Figure 7B.

Appropriate correction is required.

Claim Objections

8. Claim 6 is objected to because of the following informalities: a comma should be inserted between the last two items in the list of alternatives provided in the claim (i.e. before the phrase "and an along of ..."). Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-8 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are each drawn to compositions comprising a viral envelope protein and a stabilizing peptide capable of disrupting the formation of any intermediate of any viral envelope protein that is necessary for viral fusion and entry. It is not clear what the relationship is between the viral envelope protein and the stabilizing peptide, or what is being referred to by the phrase "structural intermediates." I.e., it is not clear from the claims if the stabilizing peptides are intended to bind to, and disrupt formation of conformational intermediates of, the referenced envelope proteins (thereby associating all three elements), or if the structural intermediates referred to are separate and distinct from the referenced envelope proteins. Clarification of the relationship among the various components of the claimed compositions is required.

11. Claims 1-5, 7, 8, and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims read on compositions comprising a viral particle or viral envelope protein and a stabilizing protein that is "effective to disrupt formation of one or more structural intermediates necessary for viral fusion and entry." It is unclear what is meant by the quoted phrase. There is no indication what is meant by a "structural intermediate" in the claim. It is unclear if such structural intermediates relate in some fashion to the viral particles or envelope proteins also present in the claim, or if some other "structural intermediate" involving the stabilizing peptides is intended. Clarification of the claim language is required. It is suggested that the claims refer to (e.g.) a structural intermediates necessary for viral entry and fusion of the envelope protein (or an envelope protein of the non-infectious viral particle) in the presence of a cell surface receptor. See e.g., App., page 10, lines 20-23. Clarification of the claim language is required.

12. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims read on an immunogenic composition comprising a viral envelope protein, a stabilizing peptide, and a viral cell surface receptor, wherein the stabilizing peptide "is capable of associating" with the envelope protein to form a stabilized fusion-active structure. It is unclear from the claim language if the claimed immunogenic composition requires that the stabilizing peptide is bound to the envelope protein (i.e. if the claims are intended to read on a complex of the identified elements), or if the composition merely requires the presence of the

stabilizing peptide without necessarily requiring that the various components are bound together (i.e. if the claims are not intended to read on both complexes of the elements, and mixtures of the elements without requiring that complexes be formed).

Clarification is required. For the purposes of this action, and in view of the discussion of the claimed invention in the application, the claims are read as requiring the formation of a complex among the three identified elements of the claimed compositions.

13. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim is directed to embodiments of the claimed invention wherein the stabilizing peptide comprises SEQ ID NO: 1, or a peptide "functionally equivalent" thereto. The claim is rejected because it is not clear what the scope of the phrase "functionally equivalent" is. SEQ ID NO: 1 is disclosed in the application as a stabilizing peptide with respect to the HIV-1 envelope protein gp41. See e.g., page 21. However, claim 6 nowhere limits the functional equivalents of SEQ ID NO: 1 to embodiments wherein the peptide is a stabilizing peptide with respect to HIV-1 gp41. Further, claim 1, from which claim 6 depends, is drawn to stabilizing peptides with respect to any viral envelope protein. It is therefore unclear if the "functionally equivalent" peptides of claim 6 are intended to include stabilizing peptides with respect to any virus, or stabilizing peptides with the specific gp41 binding and stabilizing activities of the peptide of SEQ ID NO: 1. Because it is not clear what function is intended to define the scope of "functionally equivalent" peptides in the claim, the claim is rejected as indefinite.

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 1, 2, 4, 6-8, and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are drawn to a genus of compositions comprising any viral envelope protein, and any stabilizing peptide that is capable of disrupting the formation of one or more structural intermediates necessary for viral fusion and entry.

The following quotation from section 2163 of the Manual of Patent Examination Procedure is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus... See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.
>
> A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Thus, when a claim covers a genus of inventions, the specification must provide written description support for the entire scope of the genus. Support for a genus is generally found

where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed.

In support of the presently claimed genus of compositions, the application provides a description of the fusion and entry of HIV into CD4+ cells through the gp41/gp120 conjugate, and in particular through the various structural conformations of the gp41 protein. Page 5. The application provides examples of potential stabilizing peptides that can inhibit the formation of certain intermediate stages of the gp41 protein during HIV cell fusion and entry. See e.g., page 19. However, the application provides no identification of any other viral proteins with intermediate structures such as those of the gp41 protein, or of any stabilizing peptides with respect to such other viral envelope proteins.

It is noted that the art indicates that there are structural relationships between the HIV gp41 envelope protein and those of certain other viruses. See e.g., Gallaher et al., AIDS Res Human Retrovir 5: 431-40, at 433. Further, the art also discloses certain peptides described as capable of interfering with the infection of cells by certain other viruses. See e.g., U.S. Patents 6,518,013 (claiming methods of using peptides interfering with Epstein Barr Virus infection), and 6,479,055 (claiming methods of inhibiting respiratory syncytial virus transmission with peptides). However, while these references teach that the HIV gp41 protein shares certain characteristics with envelope (particularly fusion) proteins from other viruses, the teachings of the art do not demonstrate that those in the art were in possession of stabilizing peptides for each of these viruses.

Further, while the art does teach sequences of various (apparently) stabilizing peptides, these identified peptides demonstrate a great deal of sequence variation, showing no common

structural feature by which they can be recognized as a group. See e.g., the peptides identified in the claims of U.S. Patents 6,518,013 and 6,479,055. It is also noted that the disclosures of these references demonstrate that not every peptide identified as a potential stabilizing peptide for the indicated viruses was actually capable of performing the required functions. See e.g., Figure 27 of U.S. Patent 6,479,055 (teaching that different potential RSV peptides corresponding the DP-178 peptide of HIV resulted in various levels of antiviral activity). Thus, while the art demonstrates that those in the art were in possession of certain stabilizing peptides, the art also teaches uncertainty in which peptides from any particular viral protein would be operable stabilizing peptides.

It is noted that disclosure of multiple species within a claimed genus does not necessarily demonstrate possession of the genus. See, In re Smyth, 178 U.S.P.Q. 279 at 284-85 (CCPA 1973) (stating "where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus or combination claimed at a later date in the prosecution of a patent application."); and University of California v. Eli Lilly and Co., 43 USPQ2d 1398, at 1405 (Fed Cir 1997)(citing Smyth for support). In the present case, while there a several peptides disclosed in the art, the art also indicated uncertainty in the performance of other peptides than those actually identified in the present application. In view of the uncertainty in the art, the limited number of species provided by the art and the application, and the lack of any structural or other non-functional means for the identification of effective stabilizing peptides from the class of peptides in general, the teachings of the application do not provide sufficient written description support for the claimed genus.

16. Claims 1-8 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. For the purposes of this rejection, the claims are read as drawn to a genus of compositions comprising any stabilizing peptide against the HIV gp41 glycoprotein. The claims are generally drawn to a genus of inventions comprising any "stabilizing peptide effective to disrupt formation of one or more structural intermediates necessary for viral fusion and entry." Claim 6 is further limited to compositions comprising the elected peptide of SEQ ID NO: 1; or to peptides that are fragments, functional equivalents, homologues, or analogs of SEQ ID NO: 1.

Means of providing written description support for a claimed genus have been described above. As indicated above, two such methods of providing support include the provision of a number of species sufficient to demonstrate possession of the claimed genus, or the provision of a function and a structural correlating to that function.

In support of the presently claimed genus, the application provides examples of several peptides asserted to be capable of stabilizing the fusion-active form of the gp41 protein such that the protein is not able to complete the transformations required for HIV cell entry. Each of the peptides identified by the claims are peptides representing specific art recognized fragments of the gp41 protein. Further, all of the peptides specifically disclosed in the application represent either HIV gp41 sequences, or peptides that comprises specific and limited variations thereof.

See e.g., page 27. While the application suggests the use of fragments and variants of the disclosed peptides, the application provides no evidence to show that such fragments, or what if any variants, would be effective stabilizing peptides in the claimed compositions. Thus, in support of claims drawn to any stabilizing peptide or any peptide functionally equivalent to SEQ ID NO: 1 (i.e. peptides identified only by function), the application relies on the disclosure of peptides which are all drawn from a common representative source (i.e. a wild-type HIV particle).

In contrast to the suggestions in the application that analogues and fragments of the peptide of SEQ ID NO: 1 may used, the art indicates that the activity of this peptide (known in the art as DP-178) is sensitive to sequence modification. In particular, the art teaches "experiments demonstrate[ ] that little divergences from the original DP-178 sequence can be tolerated if antiviral activity in the picomolar range is to be retained." Wild et al., PNAS 91:9770-74, at 9772 left column (of record in the May 2001 IDS). This reference teaches that with very limited exceptions (id., teaching much reduced antiviral activity in DP-178 with truncations of up to 3 residues to N-terminus) the peptide was not amenable to deletions in its sequence. Additionally, a prior publication (Wild et al., PNAS 89: 10537-41, at 10541, also of record in the May 2001 IDS) teaches that peptides comprising modifications that disrupt the peptides stable helical structure resulted in a loss of anti-viral activity. These teachings indicate that 1) there is limited knowledge in the art as to other stabilizing peptides than those actually derived from viral particles, and 2) that even with respect to those initially drawn from such HIV particles, there is uncertainty in what modifications may be performed on the peptides without a

loss of function (i.e. there is uncertainty in the art regarding what analogs or fragments of the disclosed peptides would be operable).

In view of these teachings indicating the sensitivity of the peptide to modification, and the limited examples in the application and art of non-HIV peptide sequences that retain the requisite activity, there is insufficient written description support to demonstrate possession of the complete genus comprising any stabilizing peptide, or comprising any fragment, analog, homologue, or functional equivalent of the peptide of SEQ ID NO: 1. Thus, while the teachings in the art and application would appear to support a genus of HIV-1 or HIV-2 peptides corresponding to the peptide of SEQ ID NO: 1, there is insufficient disclosure to support the full scope of the indicated claims.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

18. Claims 1, 2, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Rimsky et al. (J Virol 72: 986-993). These claims are drawn to a composition comprising a viral envelope glycoprotein or a fragment thereof, and a stabilizing peptide wherein the stabilizing peptide is

SEQ ID NO: 1 (DP-178). Rimsky teaches an assay wherein polypeptides comprising fragments of the HIV glycoprotein gp41 are added to a composition comprising stabilizing peptide DP-178 (SEQ ID NO: 1) such that the glycoprotein fragments bind to DP-178. See, pages 989-90. Because the assay composition comprises a complex of the gp41 fragment with DP-178, the reference anticipates the indicated claims.

19. Claims 1, 2, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Kliger et al. (J Mol Biol 295: 163-68, of record in the May 2001 IDS). The claims have been described above. This reference teaches a composition comprising fragments of the gp41 glycoprotein and the DP-178 peptide. Page 166 (teaching the addition of DP-178 to a composition comprising the HIV envelope fragments). The reference therefore anticipates the indicated claims.

It is noted that the claims do not require that the there be a complex formed between the various components identified in the claims. The claims require only that the stabilizing peptide is *capable* of binding to the envelope proteins where the envelope proteins are in a particular conformation, not that it actually does so in the claimed composition.

20. Claims 1-5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Wild et al. (WO 94/02505- of record in the May 2001 IDS). These claims are drawn to an immunogenic composition comprising a viral envelope protein, a stabilizing peptide, and a viral cell surface receptor, wherein the stabilizing peptide associates with the envelope protein to form a stabilized fusion-active structure.

Wild teaches a screening method where a peptide that binds to the gp41 trimer of hairpins (DP-107) is introduced to a composition comprising MOLT-4 cells (known in the art as having the receptor CD4- see e.g., Gervaix et al., J Virol 71:3048-53, abstract) and an HIV-1 virus. The reference teaches that the peptide protected cells from viral entry. Because DP-107 is disclosed in the present application has having the same activity of the claimed stabilizing peptides (pages 14-15), and as the reference teaches compositions comprising this peptide along with an HIV envelope peptide (as part of the HIV particle) and a CD receptor (as part of the MOLT-4 cells), the reference teaches a composition comprising each of the claimed elements. Further, as the reference teaches that the peptide inhibited the viral infection of the cells, the reference inherently teaches a composition wherein the peptide has stabilized the fusion active form of the gp41 protein as part of the gp41/CD4 conjugate. The reference therefore anticipates the indicated claims.

It is suggested that the claims be amended to read on compositions comprising an isolated gp41 and an isolated CD4 receptor.

21. Claims 1-6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Bolognesi et al. (WO 94/28920- of record in the May 2001 IDS). These claims have been described above, except that claim 6 requires that the stabilizing peptide is SEQ ID NO: 1.

Bolognesi provides teachings similar to those of the Wild reference applied above. In particular, this reference provides teachings relating to the anti-HIV effects of a peptide identified as DP-178. See e.g., pages 16. This peptide is disclosed as having a sequence identical to that of SEQ ID NO: 1 in the present application. Id. On pages 104-110, the reference teaches

methods wherein the DP-178 peptide is introduced to compositions comprising an HIV virus gp41 and a CD4+ cell, and wherein the peptide inhibits viral fusion and entry to the cells. As the reference teaches that the mode of such inhibition is through the binding to the fusion-active gp41 (page 112), the reference inherently teaches compositions comprising the claimed complex of gp41, the stabilizing peptide, and CD4. As no other structural requirements are provided in the present claims, the reference anticipates the indicated claims. The requirement that the claims be immunogenic does not distinguish from the disclosed compositions as there is little doubt that the administration of a composition comprising these elements would induce some form of immune response.

It is suggested that the claims be amended to read on compositions comprising an isolated gp41 and an isolated CD4 receptor.

22. Claims 1-8 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Furata et al. (Nat Struct Biol 5: 276-79- of record in the May 2001 IDS). Claims 1-8 have been described above. Claim 30 is drawn to a product of a method involving the addition of a soluble form of a cell surface receptor to a composition comprising a viral envelope protein and a stabilizing peptide, and isolating the envelope protein/peptide complex. Thus, claim 9 reads on a composition comprising a complex of an envelope protein, a stabilizing protein, and a soluble receptor.

Furata teaches methods of contacting cells expressing an HIV envelope protein expressing protein (comprising the HIV gp120 and gp41 proteins) with a fusion protein of the DP-178 protein (a homolog/analog of SEQ ID NO: 1) and a soluble CD4 receptor. Pages 278-79.

The reference also teaches the lysing of the cell, and subsequent immunoprecipitation of the resulting complex. Because the isolated complex would be immunogenic, the reference anticipates the inventions of claims 1-6. Further, there does not appear to be any structural distinction between a complex that would be formed from the processes described in claims 7 and 9 (in which the HIV envelope protein is isolated from a virus particle), and the complex formed by the reference (wherein the same envelope protein is isolated from a cell transformed to express that protein). The reference therefore also anticipates claims 7, 8, and 30 (which reads on products of claim 9).

23. Claims 1, 2, and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Root et al. (U.S. 2001/0047080, which claims priority to U.S. provisional application 60/171042). As described above, these claims read on compositions comprising a viral envelope protein or a fragment thereof and a stabilizing peptide. Claim 6 further limits the stabilizing peptides to peptides of SEQ ID NO: 1 or functional equivalents thereof.

Root teaches a complex of a molecule identified as a 5-helix in complex with a peptide identified as a C-peptide. Page 7, Example 2. The 5-helix molecule comprises several fragments of the gp41 envelope glycoprotein. Page 3. The C-peptide comprises a portion of a gp41 C-region that is a functional equivalent to the peptide of SEQ ID NO: 1. Pages 3-4. Thus, the reference teaches a composition comprising a fragment of an HIV envelope protein and a stabilizing peptide according to the indicated claims.

Conclusion

24. No claims are allowed.

25. The following prior art reference is made of record and considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

> La Casse et al., Science 283: 357-62 (of record in the May 2001 IDS). This reference suggests the use of a fusion-active form of the HIV envelope protein as a potential HIV vaccine antigen. However, while providing a motivation for the development of the claimed invention, the reference does not suggest the claimed mode of achieving an immunogenic fusion-active HIV antigen or suggest the use of stabilizing peptides in the development of such.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

JAMES HOUSEL 10/28/05
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600